### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

WYETH,	D1 : 4:00	) ) )
v. IMPAX LABORATORIES, INC.,	Plaintiff,	)
in rat Existent Cities, inc.,	Defendant,	) ) )

## WYETH'S ANSWERING BRIEF IN OPPOSITION TO IMPAX'S MOTION TO COMPEL A RESPONSE TO INTERROGATORY NUMBER 35

MORRIS, NICHOLS, ARSHT & TUNNELL LLP Jack B. Blumenfeld (#1014) Karen Jacobs Louden (#2881) 1201 N. Market Street P.O. Box 1347 Wilmington, DE 19899-1347 (302) 658-9200 Attorneys for plaintiff Wyeth

#### OF COUNSEL:

Basil J. Lewris Linda A. Wadler Barbara R. Rudolph Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. 901 New York Avenue, N.W. Washington, D.C. 20001 (202) 408-4000

Original Filing Date: February 21, 2007

Redacted Filing Date: February 28, 2007

i.

### TABLE OF CONTENTS

		<u>Page</u>
TABLE OF CITATIONS		ii
NATURE AND STAGE OF PROCEEDINGS		1
SUMMARY OF ARGUMENT		2
STATEMENT (	OF FACTS	
A. T	The Method Claims At Issue In This Litigation	3
B. I	mpax's Allegations Regarding Alza	5
C. I	mpax's Interrogatory No. 35	8
ARGUMENT		10
	The Information Sought in Interrogatory No. 35 Is Not Relevant To Any of Impax's Invalidity Contentions	10
	Wyeth Should Not be Forced to Negate Allegations Of Inequitable Conduct That Have Not Been Pled	12
C. ]	Interrogatory No. 35 Is Impossible To Answer	14
CONCLUSION		16

#### **TABLE OF CITATIONS**

Page(s)

CASES
Eli Lilly and Co. v. Zenith Goldline Pharms., Inc., 471 F.3d 1369 (Fed. Cir. 2006)10
EMC Corp. v. Storage Tech. Corp., 921 F. Supp. 1261 (D. Del. 1996)
In re Papst Licensing, GmbH Patent Litig., 174 F. Supp. 2d 446 (E.D. La. 2001)13-14
In re: Intel Corp. Microprocessor Antitrust Litig., C.A. Nos. 05-1717-JJF, 05-441-JJF, 05-485-JJF, 2007 WL 137152 (D. Del. Jan. 12, 2007)
La Chemise Lacoste v. Alligator Co., 60 F.R.D. 164 (D. Del. 1973)11
ResQNet.com, Inc. v. Lansa, Inc., No. 01 Civ.3578(RWS), 2004 WL 1627170 (S.D.N.Y. July 21, 2004)14
Samsung Elecs. Co. v. Texas Instr. Inc., Civ. A. No. 3:96-CV-0001-P, 1996 WL 343330 (N.D. Tex. April 18, 1996)
Scripps Clinic and Research Found. v. Baxter Travenol Labs., Inc., C. A. No. 87-140-CMW, 1988 WL 70013 (D. Del. June 21, 1988)11
Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786 (3d Cir. 1984)12
Solarex Corp. v. Arco Solar, Inc., 121 F.R.D. 163 (E.D.N.Y. 1988)
STATUTES
21 U.S.C. § 355(j)1
35 U.S.C. § 271(e)(2)(A)
OTHER AUTHORITIES
Tall Di Cia Di O

1.

#### NATURE AND STAGE OF PROCEEDINGS

Wyeth filed this suit on April 5, 2006, after Impax filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), seeking approval to sell generic copies of Wyeth's successful Effexor® XR Capsules prior to the expiration of the patents-in-suit. [Complaint, D.I. 1]. Effexor® XR is Wyeth's highly successful extended release formulation of the drug venlafaxine hydrochloride, used in the treatment of debilitating psychological disorders such as major depressive disorder, generalized anxiety disorder, social anxiety disorder, and panic disorder.

Discovery began on June 23, 2006, and on September 8, 2006, Impax served on Wyeth its Second Set of Interrogatories (Nos. 20-40), including Interrogatory No. 35. Wyeth objected to Interrogatory No. 35 on several grounds, including that it seeks contentions regarding allegations of inequitable conduct that Impax has not pled, let alone pled in conformance with the strict requirements of Fed.R.Civ.P. 9. [Matterer Decl., D.I. 79, Ex. 6 at 41-42]. The parties attempted, but were not able, to reach a compromise. Impax filed its motion to compel a response to this interrogatory on February 6, 2007. [Impax Br., D.I. 78]. This is Wyeth's answering brief in opposition to Impax's motion to compel.

<sup>&</sup>quot;Matterer Decl., D.I. 79, Ex." refers to the Exhibits submitted with the Matterer Declaration that accompanied Impax's Motion to Compel a Response to Interrogatory Number 35 (D.I. 76) filed on February 6, 2007.

#### SUMMARY OF ARGUMENT

Impax argues that it is entitled to a response to Interrogatory No. 35 because it is "relevant to Impax's invalidity defense based on the Alza formulations," and because it is entitled to the identity of Wyeth employees having knowledge of the "Alza formulations." [Impax Br., D.I. 78, at 6-9]. But Interrogatory No. 35 is not relevant to any alleged invalidity defense, and does not even seek the identity of individuals having knowledge of unspecified "Alza formulations." Rather, Interrogatory No. 35 seeks Wyeth's contentions as to (1) why some unspecified information is not material to patentability and (2) why unspecified individuals had not withheld from the U.S. Patent and Trademark Office ("PTO") this unspecified information with an intent to deceive.

Inequitable conduct must be pled with particularity. *EMC Corp. v. Storage Tech. Corp.*, 921 F. Supp. 1261, 1263 (D. Del. 1996); Fed.R.Civ.P. 9(b). Not only has Impax failed to do so, but it has tried to shift the burden to Wyeth to disprove allegations that Impax has not even pled, let alone with particularity. Because Interrogatory No. 35 is not directed to any issue in this case, it is improper, and Wyeth should not be required to respond.

Impax admits that it has not pled inequitable conduct based on any alleged Alza prior art (let alone pled it with sufficient particularity to satisfy Federal Rule of Civil Procedure 9), but that it seeks Wyeth's contentions through Interrogatory No. 35 "to gather the information required to plead this theory." [See Impax Br., D.I. 78, at 10]. Impax puts the cart before the horse—the protections of Rule 9(b) limit the use of unpled (and unsubstantiated) allegations as a pretext for the discovery of evidence to support a theory of inequitable conduct. Indeed, courts have denied the kind of discovery Impax

now seeks because it amounts to nothing more than an improper "fishing expedition" that is not permitted under the Federal Rules.

Moreover, the interrogatory, on its face, is unduly burdensome, indeed impossible to answer. Interrogatory No. 35 is almost boundless in scope. It would require Wyeth to identify every employee who at any time during the prosecution of the patents in suit had some unspecified information pertaining to the Wyeth/Alza collaboration, and for each such bit of unspecified information, determine whether it was disclosed as part of the Alza patent application admittedly before the patent examiner, and if it was not, articulate all reasons why the unspecified information is not material, and articulate all reasons why the unspecified employees did not conceal the unspecified information with an intent to deceive. Impax's attempted use of such an unwieldy contention interrogatory to disprove every conceivable theory of inequitable conduct based on the Alza/Wyeth collaboration in the absence of a single properly pled allegation is clearly improper.

For at least these reasons, Impax's motion to compel an answer to Interrogatory No. 35 should be denied.

### STATEMENT OF FACTS

#### A. The Method Claims At Issue In This Litigation

Wyeth's Complaint charges Impax with infringing three Wyeth patents—U.S. Patent Nos. 6,274,171 B1 ("the '171 patent"), 6,403,120 B1 ("the '120 patent"), and 6,419,958 B2 ("the '958 patent") (collectively "Wyeth's patents")—covering Wyeth's Effexor® XR pharmaceutical products and the use of those products. [Complaint, D.I. 1]. Under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A), Impax infringed Wyeth's

patents by submitting an ANDA to the FDA seeking approval to market its generic copies of Effexor® XR capsules before the expiration of those patents.

Wyeth contends that Impax infringes claims 20-25 of the '171 patent, claims 1-6 of the '958 patent, and claims 1, 2, 13 and 14 of the '120 patent, which relate to the once-daily, oral administration of an extended release formulation of venlafaxine hydrochloride that provides specific pharmacokinetic and physiological effects (e.g., a peak blood plasma level at specified blood plasma concentrations or at specified times, therapeutic relief from the condition being treated, and diminished incidences of nausea and emesis). Claim 20 of the '171 patent is an example of the asserted claims, all of which are method claims:

20. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine hydrochloride in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

In its opening brief, Impax focuses on claim 1 of the '171 patent, which is not asserted in this case. [Impax Br., D.I. 78, at 2]. That claim describes a specific embodiment of an extended release formulation having narrowly defined ingredients. In contrast, the method claims that Wyeth has asserted in this case, such as claim 20 above, do not require specific ingredients other than the active pharmaceutical ingredient, venlafaxine hydrochloride. Impax's further implication that the asserted method claims are somehow limited to the administration of this narrowly drawn embodiment is based on an improper re-drafting of the claims to incorporate specific ingredients that are recited in claim 1, but not recited in the asserted method claims. [Id.].

#### REDACTED

#### B. Impax's Allegations Regarding Alza

Impax has not pled any inequitable conduct defense based on any Alza reference or on the Alza/Wyeth collaboration.<sup>2</sup> Consistent with its pleadings, Impax also has failed to include any such allegation in its answer to Wyeth's interrogatory seeking Impax's contentions regarding its unenforceability defenses.

Instead, Impax contends that a published Alza PCT patent application (WO 94/27589) inherently anticipates one or more of the asserted claims of Wyeth's patents. [Impax Br., D.I. 78, at 4]. But during the prosecution of Wyeth's patents, the PTO examiner fully considered the Alza PCT application and concluded that it did not anticipate or render obvious any claim at issue in this litigation. The PTO examiner was correct that the Alza PCT application does not disclose the claimed invention. There are no *in vivo* tests reported in the Alza PCT application, and no pharmacokinetic data (e.g., Cmax or Tmax) reported for any formulation. Indeed, there are insufficient details in the Alza PCT application to even fully describe, much less reproduce, any formulation. Consequently, Impax bears a heavy burden in proving that the Alza PCT application is invalidating prior art.

Impax further argues that certain failed OROS® formulations developed during the Wyeth/Alza collaboration anticipate one or more of the asserted claims under §§ 102(a), 102(b), 102(f), and 102(g)(2). [Impax Br., D.I. 78. 7-8].

5.

Impax argues that it asserted in its "First Amended Complaint [sic, Answer]" that "the patents-in-suit are unenforceable for inequitable conduct." [D.I. 78 at 2]. The inequitable conduct defense set forth in its First Amended Answer, however, is not based, either in whole or in part, on any Alza formulation or reference. Impax has not pled inequitable conduct based upon any Alza work.

REDACTED

6.

3

#### **REDACTED**

7.

Significantly, Wyeth produced non-privileged documents pertaining to the Wyeth/Alza collaboration on the failed OROS® formulations to Impax. Furthermore, Impax has subpoenaed documents bearing on this research project directly from Alza. Impax, therefore, has not been denied discovery on underlying facts pertaining to its allegations of anticipation and obviousness.<sup>4</sup>

Finally, Impax notes that Alza has sued Wyeth in the Eastern District of Texas, alleging infringement of U.S. Patent No. 6,440,457 ("the Alza patent").<sup>5</sup> [Impax Br., D.I. 78, at 2]. This action, however, concerns Impax's infringement of Wyeth's

Wyeth strenuously denies that any Wyeth/Alza collaboration and/or Alza publication renders any claim of Wyeth's patents invalid. But because Impax has sufficiently pled its allegations of anticipation and obviousness (which are not subject to the Rule 9 particularity requirement), Wyeth has provided this discovery.

The Alza patent contains essentially the same disclosure as the published Alza PCT application. Like the Alza PCT application discussed above and unlike Wyeth's patents-in-suit, the Alza patent neither discloses, nor claims, any specific pharmacokinetic results.

patents, not the Alza patent that is the subject of the Alza litigation. The Alza litigation is simply not relevant here. In fact, that litigation is presently stayed pending the results of a reexamination of the Alza patent ordered by the PTO.

### C. Impax's Interrogatory No. 35

Against this backdrop, Impax served Interrogatory No. 35:

To the extent WYETH contends that, during the prosecution of the PATENTS IN SUIT, WYETH or the NAMED INVENTORS were not aware of ALZA's **EXTENDED** RELEASE development of an FORMULATION comprising VENLAFAXINE beyond the disclosure in publication WO 94/27589, that the information known about ALZA's development was not material to patentability, and/or that information known about ALZA's development was not withheld from the PTO with the intent to deceive, IDENTIFY all factual and legal bases for such contentions, including all PERSONS who have knowledge of such bases, what knowledge each PERSON has, and all DOCUMENTS that evidence such bases, for WYETH's contention.

[Matterer Decl., D.I. 79, Ex. 4 at 12, Interrogatory No. 35 (emphasis added)].

Even a cursory review this interrogatory reveals that it is seeking:

- Wyeth's contentions regarding whether WYETH<sup>6</sup> or the named inventors were aware of Alza's undefined "development" of an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE to the extent it is "beyond the disclosure in publication WO/94/27589";
- Wyeth's contentions regarding materiality of an undefined "ALZA's development";

<sup>&</sup>quot;WYETH" is defined by Impax to include "any related companies, parents, divisions, or subsidiaries, past or present, located in the U.S. or abroad, and the past or present directors, officers, employees, agents, representatives or attorneys thereof." [Matterer Decl., D.I. 79, Ex. 4 at 1 (Impax's Second Set of Interrogatories)].

- Wyeth contentions regarding whether information regarding the undefined "ALZA's development" was withheld from the PTO;
- Wyeth's contentions regarding whether the undefined "ALZA's development" was withheld from the PTO with an intent to deceive and
- Wyeth's factual and legal basis for each of the above contentions.

On its face, Interrogatory No. 35 is directed to the issue of inequitable conduct. It is not designed to discover facts relevant to the issues of anticipation and/or obviousness or the identity of individuals with knowledge of those facts.

Accordingly, Wyeth objected to Interrogatory No. 35 as calling for information protected by the attorney-client privilege and/or work product immunity; as overly broad in seeking the identification of "all PERSONS who have knowledge of such bases;" and as unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. [Matterer Decl. Ex. 6, D.I. 79, at 41-42]. Wyeth further objected to Interrogatory No. 35 as irrelevant and premature in calling for Wyeth to rebut contentions for which Impax bears the burden of proof, and specifically noting that "Impax has not set forth allegations or contentions regarding inequitable conduct on the basis of 'ALZA's development of an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE." [Id. at 42]. Wyeth reiterated this position in subsequent correspondence, but indicated that it might supplement its response if Impax could "articulate the relevance of the requested information." [Louden Decl. Ex. 1 at 7]. Although the parties subsequently engaged in extensive discussion and correspondence in which each side proffered compromise proposals, they were not able to resolve this dispute. [Matterer Decl., D.I. 79, Ex. 8; at 2; Id, Ex. 9, at 2-3; Id., Ex. 10 at 2; Id., Ex. 11 at 2; Id., Ex. 12; Id., Ex. 13 at 2]. Impax then filed its motion to compel.

#### **ARGUMENT**

A. The Information Sought In Interrogatory No. 35 Is Not Relevant To Any Of Impax's Invalidity Contentions

Impax insists that it is entitled to take discovery regarding formulations developed in the course of the Wyeth/Alza collaboration "because this information is relevant to Impax's invalidity defense based on the Alza formulations." [Impax Br., D.I. 78, at 6]. What Impax ignores, however, is that Wyeth has provided documents relating to its collaboration with Alza, and has made clear that additional information is forthcoming.

Interrogatory No. 35, however, is not directed to the facts of the Wyeth/Alza collaboration. Rather, it seeks Wyeth's contentions regarding Wyeth's or the named inventors' subjective "awareness" of unspecified information relating to the Wyeth/Alza collaboration, the materiality of that information, and whether "that information known about ALZA's development was not withheld from the PTO with the intent to deceive." [Matterer Decl., D.I. 79, Ex. 4 at 12, Interrogatory No. 35]. Contentions regarding materiality and intent to deceive pertain to inequitable conduct, not validity. See Eli Lilly and Co. v. Zenith Goldline Pharms., Inc., 471 F.3d 1369, 1381 (Fed. Cir. 2006) ("To assess inequitable conduct, the trial court must determine whether the withheld reference meets a threshold level of materiality. Then, the trial court must also determine whether the evidence shows a threshold level of intent to mislead the PTO. After finding the threshold levels of materiality and intent, the trial court then balances those factors.")(internal citations omitted). These issues have no bearing on any of Impax's invalidity defenses.

Indeed, Impax cannot even explain why Wyeth's or the inventors' subjective "awareness" of any aspect of the Wyeth/Alza collaboration has anything to do with its invalidity defenses. Nevertheless, Wyeth's proposed compromise question ("Does Wyeth contend that as of March 25, 1996, the named inventors were unaware that Alza was attempting to formulate a formulation comprising venlafaxine hydrochloride?") would have provided information, insofar as it was directed to the inventors' "awareness" prior to the filing date of the patents in suit—the time period relevant to an invalidity analysis. [Matterer Decl., D.I. 79, Ex. 11, at 2]. In rejecting this offer, Impax made clear that Interrogatory No. 35 was not a legitimate attempt to conduct discovery with respect to invalidity.

Impax's reliance on Scripps Clinic and Research Found. v. Baxter Travenol Labs., Inc., C. A. No. 87-140-CMW, 1988 WL 70013 (D. Del. June 21, 1988); In re: Intel Corp. Microprocessor Antitrust Litig., C.A. No. 05-1717-JJF, 05-441-JJF, 05-485-JJF, 2007 WL 137152 (D. Del. Jan. 12, 2007), and La Chemise Lacoste v. Alligator Co., 60 F.R.D. 164 (D. Del. 1973), is misplaced. There is no evidence that the motions to compel at issue in those cases relate in any way to unpled allegations of inequitable conduct. Indeed, Intel emphasizes that a party seeking discovery has the burden of demonstrating its merits. In re: Intel Corp., 2007 WL 137152, at \*5. And having failed to comply with Rule 9(b) with respect to the information sought in Interrogatory No. 35, Impax cannot satisfy this burden.

Lastly, Impax argues that it is entitled to know the identity of Wyeth employees having knowledge of the "Alza formulations." [Impax Br., D.I. 78, at 9]. But Interrogatory No. 35 does not request this information. Moreover, Wyeth has produced

to Impax documents relating to the Wyeth/Alza collaboration, thereby providing Impax with information from which it can determine the identity of Wyeth employees involved in the collaboration with Alza.

# B. Wyeth Should Not be Forced to Negate Allegations Of Inequitable Conduct That Have Not Been Pled

Fed. R. Civ. P. 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." This Court has ruled that the particularity requirement of Rule 9(b) applies to charges of inequitable conduct and is intended to give the opposing party notice of the precise misconduct alleged. EMC Corp. v. Storage Tech. Corp., 921 F.Supp. 1261, 1263 (D. Del. 1996). Pleadings under this rule must describe with particularity the nature, subject, and circumstances of the alleged misrepresentation with "precision and some measure of substantiation." See Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984). Thus, for example, pleadings of a party alleging inequitable conduct "that disclose the name of the relevant prior art and disclose the acts of the alleged fraud fulfill the requirements of Rule 9(b)." EMC Corp., 921 F. Supp. at 1263. But Impax has not identified any particular information pertaining to the failed OROS® venlafaxine hydrochloride formulations that was somehow material to patentability that was not otherwise disclosed to the PTO. Further, Impax has not identified any particular information withheld from the PTO, or any particular person(s) having an intent to deceive. Impax's First Amended Answer, Responses to Interrogatories, and even its brief in support of its motion to compel, are all completely silent on these essential details.

Although Impax has not yet pled with particularity its theory of inequitable conduct based on the withholding of any information about the Wyeth/Alza

collaboration, it argues that it requires the discovery sought through Interrogatory No. 35 "in order to gather [this] information." [Impax Br., D.I. 78, at 10]. But, contrary to Impax's argument, it is improper to use discovery to search for a factual predicate to plead inequitable conduct. See Solarex Corp. v. Arco Solar, Inc., 121 F.R.D. 163, 179 (E.D.N.Y. 1988). In In re Papst Licensing, GmbH Patent Litig., 174 F. Supp. 2d 446 (E.D. La. 2001), the court found that, like Impax here, the alleged infringer had not properly pled its inequitable conduct defense. The defendant in Papst argued that "through discovery, it will likely uncover additional facts to support its defense." 174 F. Supp. 2d at 449. The Papst court denied the requested discovery stating: "IBM should not be allowed to use discovery to adequately plead its inequitable conduct defense." Id. at 449-450.

Here, as in Papst, Impax's stated intent to use Interrogatory No. 35 to "gather information" sufficient to support a pleading of inequitable conduct with respect to Alza is directly contrary to the intent of Rule 9(b) to limit the use of such allegations as a pretext for the discovery of unknown wrongs or "as a launching pad for extensive or unwarranted discovery." Samsung Elecs. Co. v. Texas Instr. Inc., Civ. A. No. 3:96-CV-0001-P, 1996 WL 343330 at \*3 (N.D.Tex April 18, 1996)("The application of Rule 9(b) is especially appropriate in the case at hand, given Samsung's implications that discovery may serve to elucidate and bolster its pleadings."). Likewise, the court in Chiron Corp. v. Abbott Labs. stated that Rule 9(b) is designed to prevent a party from "launching a 'fishing expedition,' allowing the accuser to embark on wide-ranging discovery upon a thimble-full of facts." 156 F.R.D. 219, 221, (N.D. Cal. 1994)(striking amended answer as insufficient under Rule 9(b) for failing to explain how a declaration submitted to the PTO allegedly misled the examiner).

Impax's Interrogatory No. 35 is just such an improper fishing expedition, which impermissibly attempts to buttress unpled allegations of inequitable conduct. See Papst, 174 F. Supp.2d at 449. Indeed, absent the necessary specificity in its pleadings, Impax has failed to establish a need for any discovery on this issue. See ResQNet.com, Inc. v. Lansa, Inc., No. 01 Civ.3578(RWS), 2004 WL 1627170 at \*4 (S.D.N.Y. July 21, 2004) (refusing to allow the deposition of the attorney who prosecuted the patents in suit in search of evidence of inequitable conduct because Lansa's pleading did not specify what prior art was allegedly concealed from the PTO.)

Because Impax has not pled inequitable conduct with respect to any aspect of the Alza/Wyeth collaboration, Impax's motion to compel a response to Interrogatory No. 35 should be denied.

#### Interrogatory No. 35 Is Impossible To Answer C.

Moreover, Interrogatory No. 35 is completely improper in requiring Wyeth to disprove phantom allegations of inequitable conduct. Impax's interrogatory would require Wyeth to investigate theoretical allegations and formulate contentions in a And, irrespective of whether Impax should ultimately allege a theory of inequitable conduct based on the Wyeth/Alza collaboration, Interrogatory No. 35 is unduly burdensome, if not impossible, to answer.

On its face, Interrogatory No. 35 provides no guidance as to the information Impax seeks. For example, the interrogatory is not limited to the inventors and those persons involved in the prosecution of Wyeth's patents. The interrogatory thus would require Wyeth to identify every person at Wyeth who had some knowledge about the Wyeth/Alza collaboration at any time during the years Wyeth's patents were prosecuted at the PTO. Furthermore, it is unclear what aspect of "Alza's development," whether planning, formulation, dissolution, clinical testing, etc., was supposedly known by these unspecified persons. Indeed Impax's interrogatory would require Wyeth to do an analysis of Alza's development to determine what information is "beyond the disclosure in publication WO 94/27589." [Matterer Decl., D.I. 79, Ex. 4, at 12, Thus, for each such person identified by Wyeth, above, Interrogatory No. 35]. Interrogatory No. 35 would require Wyeth to (1) determine whether and to what extent the information he or she has is "beyond the disclosure" in the Alza PCT application; (2) determine why that information is not material; and (3) determine why that information was not withheld from the PTO with an intent to deceive—even though the person may have had no connection with the prosecution of the patents, and even though the information may have had no relevance to any issue of patentability.

This is an impossible burden. It is beyond the scope of permissible discovery to require Wyeth to rebut, in a vacuum, every possible theory of inequitable conduct where no such allegations are properly at issue in this litigation. In light of these obvious failings, Wyeth should not be forced to respond to Interrogatory No. 35.

#### **CONCLUSION**

For the foregoing reasons, the Court should deny Impax's motion to compel a response to its Interrogatory No. 35.

#### MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Filed 02/28/2007

/s/ Karen Jacobs Louden (#2881) Jack B. Blumenfeld (#1014) Karen Jacobs Louden (#2881) 1201 N. Market Street P.O. Box 1347 Wilmington, DE 19899-1347 (302) 658-9200

Attorneys for plaintiff Wyeth

#### OF COUNSEL:

Basil J. Lewris Linda A. Wadler Barbara R. Rudolph Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. 901 New York Avenue, N.W. Washington, D.C. 20001 (202) 408-4000

February 21, 2007 747211.1

#### CERTIFICATE OF SERVICE

I, Karen Jacobs Louden, hereby certify that on February 21, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

> Mary B. Matterer MORRIS, JAMES, HITCHENS & WILLIAMS, LLP

I also certify that copies were caused to be served on February 21, 2007 upon the following in the manner indicated:

#### BY HAND

Mary B. Matterer Morris, James, Hitchens & Williams 500 Delaware Avenue Suite 1500 Wilmington, DE 19899

#### BY FEDERAL EXPRESS

M. Patricia Thayer John M. Benassi Jessica R. Wolf Heller Ehrman LLP 4350 La Jolla Village Drive San Diego, CA 92102

> /s/ Karen Jacobs Louden (#2881) klouden@mnat.com

#### **CERTIFICATE OF SERVICE**

I, Karen Jacobs Louden, hereby certify that on February 28, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer MORRIS, JAMES, HITCHENS & WILLIAMS, LLP

I also certify that copies were caused to be served on February 28, 2007 upon the following in the manner indicated:

#### **BY HAND**

Mary B. Matterer Morris, James, Hitchens & Williams 500 Delaware Avenue Suite 1500 Wilmington, DE 19899

#### BY FEDERAL EXPRESS (on 3/1/07)

M. Patricia Thayer John M. Benassi Jessica R. Wolf Heller Ehrman LLP 4350 La Jolla Village Drive San Diego, CA 92102

/s/ Karen Jacobs Louden

Morris, Nichols, Arsht & Tunnell LLP 1201 N. Market Street P.O. Box 1347 Wilmington, DE 19899 (302) 658-9200 klouden@mnat.com